K003604

Section II 510(k) Summary and Certification

FEB - 7 2001

Adapters with X-Coating

Submitter Information:

Name and Address:
Olson Medical Sales, Inc.
28 Howe Street
Ashland, MA 01721

Contact Person:
Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: November 14, 2000

Device Names:

Proprietary Name:	Adapters with X-Coating
Common Name:	Adapters
Classification Name:	Adapter, Stopcock, Manifold, Fitting Cardiopulmonary Bypass

Predicate Device:

The Adapters with X-Coating that are the subject of this premarket notification are substantially equivalent to the predicate devices, the uncoated adapters, which are legally marketed and have been in interstate commerce prior to May 28, 1976. As such, the predicate adapters are considered to have *preamendment* status.

Intended Use:

The Adapters with X-Coating are intended to be used to interconnect tubing and other devices within a circuit during extracorporeal bypass procedures.

The adapters are intended for use in procedures lasting up to 6-hours in duration.

The blood-contacting surfaces of the adapters are coated with X-Coating, which is a biocompatible coating that reduces the adhesion of platelets to the surfaces.

Principles of Operation and Technology:

The adapters that are the subject of this premarket notification perform by providing a connection between devices within a bypass circuit, effectively establishing a conduit between the devices for the flow of blood and other extracorporeal fluids.

Design and Materials:
The Adapters with X-Coating are of various designs (straight adapters, Y-Adapters, and slip adapters), each of which provide for the flow of blood and extracorporeal fluids through the bypass circuit. Each adapter is molded from polycarbonate resin.

Performance Evaluations:
The performance of the Adapters with X-Coating submitted in this premarket notification is substantially equivalent to the performance of the uncoated adapters. The following tests were conducted to demonstrate equivalence in performance:

- Visual Examinations
- Dimensional Analysis
- Leakage Testing (Mechanical Integrity)
- Pull Force (Against Tubing) Analysis

Substantial Equivalence Comparison:
The Adapters with X-Coating are substantially equivalent to the uncoated adapters as follows:

- Intended Use: The Adapters with X-Coating and the uncoated adapters are intended to be used to interconnect tubing and other devices within a circuit during extracorporeal bypass procedures. Both are intended to be used during procedures lasting up to 6 hours duration.

- Principles of Operation and Technology: The Adapters with X-Coating and the uncoated adapters each utilize the same technologies in the operation of the devices. The adapters provide a connection between devices within a bypass circuit, effectively establishing a conduit between the devices for the flow of blood and other extracorporeal fluids.

- Design and Materials: The design and the materials of the Adapters with X-Coating and the uncoated adapters are exactly the same with the exception of the X-Coating polymer that is applied to the coated adapters.

- Performance: Comparisons of the performance of the Adapters with X-Coating and the uncoated adapters were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the coated and uncoated devices.

Substantial Equivalence Summary:
In summary, the Adapters with X-Coating and the uncoated adapters are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Olson Medical Sales, Inc. conducted biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Olson Medical Sales, Inc. conducted studies for materials characterization, including physico-chemical profiles and FT-IR scans.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

- Safety evaluations of the polymer coating were conducted by Terumo Corporation (Japan). Those studies include:

    - Acute Systemic Toxicity Testing (in Rats)
    - Genotoxicity Testing – Bacterial Reverse Mutation
    - Genotoxicity Testing – Chromosome Aberration
    - Sensitization (in Guinea Pigs)

Conclusion:

In summary, the Adapters with X-Coating are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated adapters which have *preamendment* status (i.e., legally marketed and in interstate commerce prior to May 28, 1976).

Olson Medical Sale's statement that these devices are substantially equivalent to any other devices is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 7 2001

TERUMO Cardiovascular Systems Corporation
c/o Mr. Garry A. Courtney
Regulatory Affairs Specialist
OMS/TCVS
125 Blue Ball Road
Elkton, MD 21921

Re: K003604
Trade Name: Adapters with X-Coating
Regulatory Class: II (two)
Product Code: DTL
Dated: November 20, 2000
Received: November 21, 2000

Dear Mr. Courtney;

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): _____

Device Name: **Adapters with X-Coating**

Indications For Use:

Intended Use Described In The 510(k):

The Adapters with X-Coating are intended to be used to interconnect tubing and other devices within a circuit during extracorporeal bypass procedures.

The adapters are intended for use in procedures lasting up to 6-hours in duration.

The blood-contacting surfaces of the adapters are coated with X-Coating, which is a biocompatible coating that reduces the adhesion of platelets to the surfaces.

Garry A. Courtney 11/20/2000

Garry A. Courtney
Regulatory Affairs
Olson Medical Sales, Inc.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

2/6/11

Division of Cardiovascular & Respiratory Devices
510(k) Number K003604